

EXHIBIT 5-c

1 record, and they are extensive, the proper and most
2 expeditious way to deal with the case is to remand to the
3 agency to get it augmented.

4 THE COURT: And you don't call this a glaring error?

5 MR. DESMARAIS: But it is not extensive. And that's
6 the difference that I am trying to draw here. And there are
7 cases that talk about offering limited discovery to augment
8 the record, and that's all we are looking for here. We are
9 not looking to, you know, say that the record as put forward
10 is totally unworkable. That's not our point at all.

11 Our point is only, we know that there are these
12 things missing, and we articulated them in our brief with
13 specificity, and we have then attached document requests and
14 interrogatories. If the PTO answers those document requests
15 and answers those interrogatories, the record will be complete
16 and we can move to summary judgment actually quite
17 expeditiously. We are not looking for depositions and we are
18 not looking to do regular civil litigation discovery.

19 And I think there are cases that say in those sorts
20 of circumstances where there are specific things missing from
21 the record, you know, Courts have allowed limited discovery.
22 In fact, we cited some of the cases in our brief where there
23 were document requests or answer to an interrogatory. And
24 that's where we go into the next issue.

25 So, I think, first of all, on the discovery, the

1 plaintiffs are asking for different things. Right. And I
2 think GSK's approach here is very modest and could be dealt
3 with very swiftly by the Patent Office simply answering the
4 specific document requests and specific interrogatories and
5 their record will then be complete.

6 Now, the PTO's response to that when you look at
7 their brief, they did a point-by-point rebuttal to the things
8 we said were missing from the record. It's instructive what
9 they actually said. They didn't say, GSK, you are wrong,
10 those things don't exist.

11 In fact, for each of the five categories that we
12 laid out, and we laid out the five categories from our briefs:
13 The documents, these analyses before January '06; the
14 documents showing why they made the changes from the proposed
15 rules to the final rules after the comment period; the
16 postpromulgation, augmentation and guidelines; the
17 communications with third-parties; and the alternative rules
18 they considered, those were the five categories we outlined in
19 our brief, their responsive brief didn't say that documents
20 from those five categories don't exist. They said, oh, you
21 don't need those, they are irrelevant, they are transmittal,
22 or they are deliberative. Right.

23 Now, the interesting thing about the way they are
24 handling the deliberative privilege, it goes against all the
25 cases because when you look at the declaration they submitted

1 to support the deliberative privilege, they never even looked
2 at the documents that are missing.

3 The declaration here from McDowell says-- Let me
4 pull that out, excuse me. Oh, here, it is. Yeah. Okay.

5 The declaration from McDowell says, if the Court
6 orders this limited discovery, we'll have to go and collect
7 and review the documents. This is paragraph 7. And paragraph
8 eight of her declaration says, you know, this would constitute
9 e-mails and memoranda and drafts and contributions and paper,
10 issued papers and meeting notes and more, could be hundreds,
11 could be thousands. They don't even know.

12 So, when you look at the case law on deliberative
13 privilege, their own declaration proves they haven't done what
14 they are required to do under the rules.

15 Under the rules, if they have documents that were
16 considered or indirectly, you know, directly or indirectly,
17 they either have to be in the administrative record or it is
18 the PTO's burden to have someone in the agency review the
19 documents and articulate with specificity, these ones are
20 deliberative.

21 There is no way they could have met that burden
22 because they haven't even collected and reviewed the documents
23 by their own declaration.

24 So, how do we solve this problem? It is actually
25 quite simple? You know, if Your Honor orders them to answer

1 the document requests and the interrogatories we served, which
2 are attached to our papers which are targeted to this things
3 they admit are not in the record, answer those.

4 And just like any litigation, if there are things in
5 response to those specific requests that they want to claim
6 the deliberative privilege on, they have a right to do that,
7 but they need to tell us, they need to have somebody actually
8 review the document, say that it is deliberative and say why
9 it is deliberative.

10 That way and only that way can we then pick through
11 those things and add the ones that aren't into the record
12 where they belong.

13 And I tell you, they cannot, it cannot be the case
14 that they are claiming the deliberative privilege from models
15 and analyses that they have done about the impact of these
16 rules on pending patent applications. That is not the
17 deliberative privilege. That is underlying factual
18 information. They admit it exists, it's not in the record,
19 and they haven't even gone to collect and review it.

20 So, we don't need to go through the cumbersome
21 process of going to the District Court and having it remanded
22 because we fall within those cases where simple targeted
23 discovery will get at the problem, will augment the record.

24 And frankly, there is no reason not to do it here.
25 This case has a huge impact on the public. There are at the

1 time of the PI hearing, I am sure it is even more now, almost
2 a million pending patent applications that are affected by
3 these rules. These rules affect every single new patent
4 application.

5 So, the burden--

6 THE COURT: I am aware of the significance of the
7 case.

8 MR. DESMARAIS: Yeah. For the PTO to come in and
9 say, well, you know, it is burdensome for us to complete the
10 administrative record, I think the Court should not hear that
11 sort of argument on a case where these rules have a huge
12 impact on the public.

13 The PTO needs to justify the rules. If they are
14 going to hold back items from the administrative record that
15 they admit exist, they need to follow the rules that every
16 other litigant follows, which is you have somebody review the
17 documents, you confirm that in fact they are deliberative, and
18 you tell why and you send that to us, we can then challenge it
19 in the litigation context, and only that way does the truth
20 come out.

21 Otherwise, where are we? The PTO has unfettered,
22 unchecked autonomy to put whatever administrative record they
23 want. Your Honor can't review it. They are hiding it from
24 judicial review. They are keeping it out of a litigation
25 context. And that is no way to run a litigation whether it is

1 an APA litigation or a civil litigation. They need to be held
2 to the same standards that any civil litigant is held to.

3 So, you know, GSK's requests were very limited to
4 the document requests and interrogatories and to a privilege
5 log to the extent the information is responsive to those
6 specific requests. We are not in a fishing expedition, we are
7 not looking for depositions, and we are not looking for bad
8 faith discovery.

9 THE COURT: Thank you. Ms. Wetzler.

10 MS. WETZLER: May it please the Court, Your Honor.
11 On October 31, 2007, GSK stood in court and said it was ready
12 to have this case decided in December. Tafas had already
13 agreed to a schedule, roughly the same schedule if the
14 preliminary injunction had been put in place.

15 Proceeding on that schedule would have required
16 going forward presumably without discovery, without a
17 privilege log. And the plaintiffs were prepared to do that.

18 Now that there is a preliminary injunction, we have
19 a completely different approach that the plaintiffs are
20 taking. They have flooded the Court--

21 THE COURT: That's not surprising, is it?

22 MS. WETZLER: It is not surprising, Your Honor, but
23 it's telling that they were previously prepared to have this
24 case go forward without discovery and without a privilege log
25 in order to have a hearing just next month, almost this month.

1 And it is telling because it indicates the real need for this
2 and the fact that there is not a real need for this.

3 And the reason, there are numerous reasons. The
4 plaintiffs have now had ample opportunity to present them to
5 the Court, and they simply demonstrate that discovery is not
6 needed in this case.

7 I would like to start with what has been completely
8 missing from both plaintiff's presentations today, and that is
9 the notion that there is a presumption of regularity when an
10 agency certifies an administrative record. Your Honor said,
11 well, Ms. Wetzler has said that this is, that this is a
12 complete record. Your Honor, it's not just me saying that.
13 This is not an argument of counsel.

14 THE COURT: I understand that.

15 MS. WETZLER: Yes. It's an argument, it is a
16 certification by the agency that is entitled to a presumption
17 of regularity unless it is rebutted. And it has not been
18 rebutted here.

19 THE COURT: Help me understand better than I do why
20 materials generated prior to January 2006 aren't appropriately
21 included in the record?

22 MS. WETZLER: Your Honor, we have a few different
23 arguments on that point. The first is, it's important to keep
24 in mind what the focus of the review that this Court is doing
25 is. And that focuses on the--

1 THE COURT: The focus is on the final rules.

2 MS. WETZLER: Is on the final rules.

3 THE COURT: In the circumstances presented here, why
4 shouldn't that focus include, at least on the peripheral
5 vision, the events that occurred prior to the final rule
6 making?

7 MS. WETZLER: Well, Your Honor, in fact we have
8 included any nondeliberative materials having to do with the
9 proposed rules.

10 GSK itself noted that there were more, there were
11 400 pages that were generated prior to January 2006. They say
12 that on page 1 of their brief. So, there are 400 pages that
13 are in the record. And there are vast deliberative materials.

14 Your Honor can certainly understand that when an
15 agency is trying to decide what rules to put forward, it's
16 clearly going to be having deliberations. And this is--

17 THE COURT: I hope so.

18 MS. WETZLER: Of course, we all hope so, or else we
19 wouldn't have reasoned decision making by an agency. And so,
20 consequently, here again, what plaintiffs are asking for and
21 speculating exists are deliberative materials. And to the
22 extent they are not deliberative, we have offered 400 pages in
23 the record that were produced by the proposed rule. That's
24 GSK's count.

25 Then turning back to the question of there being a

1 presumption of regularity and the fact that it hasn't been
2 rebutted.

3 In order to rebut that, we need, the plaintiffs
4 would have to show that there is, that there is bad faith or
5 that the record is so incomplete as to frustrate judicial
6 review.

7 Your Honor, this is the 127 page Federal Register
8 notice that explains, that states the reasons why the agency
9 has taken the final action that it did.

10 There is ample opportunity for the Court to review
11 this Federal Register notice and focus on what is the required
12 focus of the Court's inquiry, which is the stated reasons.
13 And the reasons are clearly stated in this document, and they
14 are substantiated in the administrative record which is nearly
15 10,000 pages long.

16 Turning then to the question of deliberative
17 materials. They are not part of the record. It's not simply
18 that they are privileged, it is that they are not part of the
19 record.

20 The personal views and the deliberations and the
21 advice, the personal input of various employees of the PTO are
22 irrelevant.

23 THE COURT: And they don't contend otherwise.

24 MS. WETZLER: That's correct. And so, these
25 materials--

1 THE COURT: That's not the focus here.

2 MS. WETZLER: That's not the focus. And, therefore,
3 there is no reason that these deliberative materials should
4 have to come out either themselves in a production or through
5 enumeration in a privilege log.

6 Producing a privilege log in this case, Your Honor,
7 would be an extraordinarily burdensome task. These rules were
8 in development for more than two years. One can only imagine
9 how many, how much deliberation went into this and how many
10 memoranda and e-mails and materials exist.

11 And it's not just the task of enumerating those
12 materials, it's also the task of going back and pulling all of
13 those materials. And I want to explain so that the Court
14 isn't confused about why it is that they weren't previously
15 pulled at the time this record was generated.

16 And the reason is, the folks at PTO who worked on
17 generating the record were intimately involved in this rule
18 making and they knew where to look for the materials that make
19 up the record. They knew where all the data was, they knew
20 where all the comments were, they knew where all the
21 communications.

22 The only thing that they were not reviewing were the
23 deliberative materials, which they knew to be in the
24 possession of 20 to 30 attorneys. Therefore, creating a
25 situation where these would not only be attorney/client

1 materials, but they would also be deliberative.

2 So, to Your Honor's point about one versus the
3 other, there is extensive overlap here. The people who--

4 THE COURT: So, they assumed that anything in an
5 attorney's possession would be covered by one or the other of
6 the privileges?

7 MS. WETZLER: No, it's not that that assumption was
8 made. It is that they knew already where the materials were
9 that were properly part of the record.

10 So, even if an attorney happened to also have that
11 material, that was-- It wasn't necessary to pull it from the
12 attorney because they had been keeping, they knew where to
13 look for the comments, for the data. And that's what is
14 reflected in the nearly 10,000 pages.

15 We have 4,000 pages of data. For plaintiffs to
16 stand now stand up and suggest there is no data to look at, no
17 models to look at, is simply absolutely unsubstantiated.

18 THE COURT: Well, are you disagreeing with Mr.
19 Desmarais about whether models were included in the record?

20 MS. WETZLER: Models were absolutely included into
21 the record. And we pointed the Court to where those were.

22 THE COURT: The models that he was talking about?

23 MS. WETZLER: I believe that, if I understood what
24 he was talking about, all of the models are in there. And I
25 can confirm with my client if you would like.